REMARKS

Claims 38-56 and 76-168 are pending in the patent application. Claims 87-118, which were previously withdrawn, have been cancelled without prejudice. Claims 38, 76, 119, 138 and 157 have been amended to recite "meat having meat pigment" to further clarify that the pigment is referring to meat pigment. No new matter has been entered. After entry of these amendments, claims 38-56, 76-86 and 119-168 remain in the patent application. The Applicants note that dependent claims 122, 141 and 160 have been withdrawn but are still pending the application.

The Applicants are also submitting herewith evidence in the form of a 37 C.F.R. §1.132 declaration by one of the co-inventors Mr. Gary R. DelDuca ("the DelDuca Fourth Declaration") (Exhibit 1) to assist in explaining the phrase "turns brown in a natural time period" and the applied references. The Applicants note that Mr. DelDuca previously submitted three declarations ("the DelDuca First, Second and Third Declarations")[1] to assist in explaining the invention, showing the non-obviousness of the invention and explaining the applied references. The Applicants are resubmitting a copy of the DelDuca Third Declaration (Exhibit 2) in response to the comment on page 8 of the Office Action that this declaration was not found in the prosecution of the application.

Reconsideration of the pending claims is respectfully requested.

I. Information Disclosure Statement (IDS)

The Applicants are concurrently submitting the Sixth IDS. The Examiner is respectfully requested to review the references and make them of record.

II. Claim Objections

Claims 38, 119 and 138 were objected to because they recite the phrase "the method comprising the acts of". The Applicants have included the language "the acts of" to further clarify that the claims are not step-plus-function claims. Thus, the phrase "the method

[1] The DelDuca First Declaration was filed with the Amendment and Response to Office Action Dated May 7, 2003. The DelDuca Second Declaration was filed with the Amendment and Reply to Office Action Dated June 14, 2004. The DelDuca Third Declaration was filed with the Amendment and Reply to Office Action Dated August 12, 2005.

comprising the acts of" is proper and the Applicants request that these claim objections be withdrawn.

III. 35 U.S.C. § 112, Second Paragraph, Rejection

The Office Action has stated that "[i]t is unclear as to what exactly the term 'the meat having pigment' means." Page 3. To obviate this rejection, the Applicants have amended claims 38, 76 and 157 to recite "the meat having meat pigment" to further clarify that this means the natural pigment as present in the meat. Therefore, this rejection on the phrase "the meat having pigment" should be withdrawn.

The Office Action also states that the phrase "turns brown in a natural time period" as recited in independent claims 38, 76, 119, 138 and 157 is indefinite. *Id.* The Applicants respectfully disagree and to assist in supporting that the phrase "turns brown in a natural time period" is not indefinite, the Applicants are submitting the DelDuca Fourth Declaration.

The phrase "turns brown in a natural time period" is a phrase that is used and understood by those skilled in the art. DelDuca Fourth Decl. ¶ 4. This phrase has been used in correspondence related to meat-packaging systems between retailers and myself. *Id.* Specifically, this phrase has been used by those skilled in the art in the context of the color of the meat pigment. *Id.*

The portion "turns brown" of the phrase "turns brown in a natural time period" means that the piece of meat has some brown, but does not mean that the piece of meat has to be 100% brown. DelDuca Fourth Decl. ¶ 6. Retailers and food packers use the phrase "turns brown" in the context of whether most customers would consider the color of the meat pigment undesirable such that the customers would not purchase the meat. *Id.* The phrase "turns brown" is frequently used by retailers and food packers and, thus, is not indefinite. *Id.* The term "natural time period" of the phrase "turns brown in a natural time period" cannot be uniquely defined because the color of the meat pigment varies between the type of meat and the conditions for displaying such meat. *Id.* at ¶ 7; *see* page 20, lines 17-26 of the present application ("The display times varied based on product type, initial microbial loads and storage conditions."). The natural time period for the meat pigment turning brown is not the same between ground beef, strip loins (strip steaks), inside portion of inside round steaks, outer portion of inside rounds steaks, and

tenderloins. DelDuca Fourth Decl. ¶ 7. For example, the natural time period in which the meat pigment turns brown is about 4 days for strip steaks, while the natural time period in which the meat pigment turns brown for tenderloin is about 1 day. *Id.*

One example of this phrase being used in the published literature is Principles and Applications of Modified Atmosphere Packaging of Food (1993), which is Exhibit A of the DelDuca Fourth Declaration. DelDuca Fourth Decl. ¶ 5. On page 283, the literature discusses the effect of the meat turning brown in connection with conventionally overwrapped trays and also discusses that the color stability is limited on the shelf-life depending on type of meat (muscle). *Id.*

In summary, the phrase "turns brown in a natural time period" as used in the context of independent claims 38, 76, 119, 138 and 157 is understood by those skilled in the art and, therefore, is not an indefinite phrase in this context. Thus, the § 112 rejection, second paragraph, rejection should be withdrawn.

IV. 35 U.S.C. § 103(a) Rejections

U.S. Patent No. 5,686,127 to Stockley ("Stockley") does not disclose, teach or suggest the use of carbon monoxide (CO). The Office Action applies a number of references -- U.S. Patent No. 3,459,117 to Koch ("Koch"); U.S. Patent No. 4,522,835 to Woodruff ("Woodruff"); and U.S. Patent No. 6,042,859 to Shaklai ("Shaklai") in an attempt to cure this deficiency in Stockley. It would not have been obvious to combine Stockley in view of other references such as Koch, Woodruff and/or Shaklai to arrive at the present invention.

V. Applicants Previously Presented Evidence Of Non-Obviousness Of Independent Claims 38, 76, 119, 138 and 157

Assuming, *arguendo*, that a *prima facie* case has been presented (which Applicants believe is not the case), the Applicants previously submitted evidence of non-obviousness in the form of (a) one declaration in the Amendment and Response to Office Action that was filed on May 7, 2003 -- the DelDuca Declaration (Exhibit A); and (b) two declarations in the Amendment and Reply To Office Action Dated June 14, 2004 – the Hunt Declaration (Exhibit 1) and the DelDuca Second Declaration (Exhibit 2). Some of the evidence presented was directed to the

understanding that those of ordinary skill in the art, prior to the Applicants' invention, believed that CO "fixed" the color of the meat pigment.

A. Prior To The Applicants' Invention, Those Of Ordinary Skill In The Art Believed That CO Fixed The Color Of The Meat Pigment

Specifically, the Applicants submitted evidence that prior to the Applicants' invention, those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment:

(a) CO not allowed with fresh meat in the U.S. since at least 1962, until Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concern of "fixing" the meat color;

(b) In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data "to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated" and that the FDA has a question "concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color.";

(c) A previously applied reference in this application "The Storage Life Of Beef And Pork Packaged In An Atmosphere With Low Carbon Monoxide And High Carbon Dioxide" from *Meat Science* to Sorheim et al. ("Sorheim") disclosed that its meat packaging systems with a modified atmosphere of "0.4% CO/60% CO_2/40% N_2 had a bright stable red colour that lasted beyond the time of spoilage." Abstract of Sorheim; and

(d) Dr. Hunt, who has extensive experience in the processing of meats using modified atmosphere packaging, stated that it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red.

B. The Applied References Of Shaklai, Koch And Woodruff Do Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

As previously discussed in the Amendment and Response to Final Office Action Dated August 12, 2005 in detail, Shaklai does not teach or suggest the claimed limitation of "wherein the carbon monoxide associated with the raw meat within the first package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time

period upon removal of the second package," that is specifically recited in independent claims 38, 76, 119, 138 and 157. Since Shaklai teaches that CO "fixes" the color of the meat pigment after exposure to the atmosphere, there would be no motivation to combine Shaklai with the other applied references in the pending rejections.

The Applicants also previously discussed the applied reference of Koch in the Amendment and Response to Final Office Action Dated August 12, 2005 in detail. In summary, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film because it would not be reasonable that exposing a relatively small quantity of CO that is gradually released from the CO-containing film to a large quantity of meat (primal cuts) would expose CO to the non-surface meat pigments.

In this Office Action, it is stated that Koch "do[es] not teach the right size of the meat, Koch et al., teach the use of their package from primal as well as the final cuts (column 3, lines 4-17)." Page 11. Koch discloses that "[o]f course, if desired, the final cuts rather than just the primal cuts may be individually wrapped in the cover such as shown in FIGS. 1 and 2, this cover preferably being replaced with a conventional cover by the retailer." Col. 3, lines 13-16. This passage, however, does not disclose, teach or suggest that the color of the meat pigment is not fixed and will turn brown in a natural time period. DelDuca Fourth Decl. ¶ 15. Furthermore, this passage has nothing to do with the statement in the Office Action directed to Koch on the meat pigment color ("Koch et al. teach a meat surface that has been exposed to CO for 7 days during storage under a modified atmosphere will remain red in color for 3 days after being removed from the modified atmosphere package[] and packaged in conventional wrapper at[] the retail outlet"). *See* page 6 of the Office Action; DelDuca Fourth Decl. ¶ 15. Rather, Koch discloses "[w]hen the primal cuts arrive at the retail outlet, the covers are removed and the meat is cut into individual steaks, roasts, etc. which may be separately wrapped in conventional wrapping materials. It has been found that meat will release a saleable red color for as long as 10 days when covered with the cover herein described for the first seven days and with a conventional cover for the remaining days."). Col. 3, lines 5-13 of Koch (underlining added); DelDuca Fourth Decl. ¶ 15.

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of the CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with Stockley, Shaklai, and/or Woodruff.

In summary, neither Shaklai nor Koch teaches or suggests that the meat pigment upon exposure to CO does not "fix" the color of the meat pigment after exposure to the atmosphere.

In this Office Action, the applied reference of Woodruff was further discussed. Woodruff does not teach or suggest that the color of the meat pigment turns brown in a natural time period. DelDuca Fourth Decl. ¶ 12. For example, Woodruff in Example 1 discloses a 0.5 lb. beefsteak that was exposed to 0.5% CO, which was nearly all absorbed two days later. *See* col. 4, lines 34-48; DelDuca Fourth Decl. ¶ 12. After being exposed in a modified atmosphere that included 16% oxygen, "the beefsteak retained its good red color, and the carboxymyoglobin color had penetrated no more deeply than it had at the end of the two days." *See* Col. 4, lines 49-54. This passage implies that the carboxymyoglobin color was still retained within the beefsteak after 6 days despite being exposed to an atmosphere with a generally similar amount of oxygen as in air (compare about 21% oxygen to 16% oxygen). DelDuca Fourth Decl. ¶ 12. It would be expected to one skilled in the art that the beefsteak would turn brown in about 2-3 days, depending on the cut of meat. *Id.* Thus, this example clearly shows that the beefsteak of Woodruff in Example 1 did not turn brown in a natural time period, but rather "fixed" the color of the meat pigment. *Id.* Similarly, in Example 1 of Woodruff, a 0.5 lb. beefsteak exposed to 2.5% CO under similar conditions also retained its good color after 6 days. *See* col. 4, line 55- col. 5, line 6; DelDuca Fourth Decl. ¶ 12.

None of the other examples of Woodruff supports a modified atmosphere package wherein the CO associated with the raw meat is adapted to be removed such that the color of the meat pigment is not fixed and turns brown in a natural time period. DelDuca Fourth Decl. at ¶ 13. Rather, the other examples of Woodruff generally disclose the condition of the meat pigment while being stored in a modified atmosphere containing CO. *Id.* In summary, Woodruff does not disclose, teach or suggest that the use of CO on meat pigment turns brown in a natural time period, but rather Woodruff teaches and suggests "fixing" the color of the meat pigment in Example 1. *Id.* at 14.

Since Woodruff does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of the CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Woodruff with Shockley, Shaklai, and Koch.

VI. Independent Claims 38, 76, 119, 138 and 157

Therefore, the submitted evidence summarized above indicates that prior to the Applicants' invention, those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment after exposure to the atmosphere.

Additionally, the Applicants presented compelling evidence directed to long-felt need in the Amendment and Response to Office Action Dated June 14, 2004 that further supports the non-obviousness of the present invention.

Therefore, independent claims 38, 76, 119, 138 and 157 are not obvious in view of Stockley, Koch, Woodruff, Shaklai or any combination thereof and, thus, should be in a condition for allowance.

VII. Dependent Claims 39-56, 77-86, 120-137, 139-156 And 158-168

Dependent claims 39-56, 77-86, 120-137, 139-156 and 158-168, which depend directly or indirectly on independent claim 38, 76, 119, 138 or 157 are not obvious in view of Stockley, Koch, Woodruff, Shaklai or any combination thereof for at least the same reasons discussed with respect to claims 38, 76, 119, 138 and 157. Thus, claims 39-56, 77-86, 120-137, 139-156 and 158-168 should be in a condition for allowance.

VIII. Conclusion

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. It is believed that no fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Jenkens & Gilchrist, P.C. Deposit Account No. 10-0447, Order No. 47097-01106USC1.

Respectfully submitted,

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